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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,231	11/26/2003	Jack Y. Vanderhoek	179.41866X00	5688
50438	7590	09/25/2006	EXAMINER	
JUNEAU PARTNERS			KIM, VICKIE Y	
P.O. BOX 2516				
ALEXANDRIA, VA 22301			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/721,231	VANDERHOEK, JACK Y.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Vickie Kim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 29-44 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 23-28 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 12/10/04.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election acknowledged***

1. Applicants' election with traverse the invention group III of claims 23-28 is acknowledged. Applicants traverse the restriction requirement. However, applicant fails to state grounds for the traversal. Therefore, the restriction requirement is deemed to be proper and maintained, and made FINAL.

As mentioned in previously office action, as not all inventions classified together, or each invention may not be anticipated by others because each invention is patentably distinct to each other as evidenced by numerous patents(see supporting documents US 6670138, 6417205, 6280737).

Furthermore, even if there were unity of classification, the search of the entire genus in the non-patent(a significant part of a thorough examination) would be burdensome. Thus, each invention is found to be independent and patentably distinct, further burdensome.

Therefore, the restriction requirement is necessary, and made FINAL.

### ***Election of Species***

2. There seems to have some confusion in election of species requirement. Although claims 24-28 are drawn to a method claims, because of they are dependent on composition claims, their dependency was incorrect or their subject matter is incorrectly claimed(see claim objection). Since number of claims are not so extensively large, although searching all the species claimed may be burdensome and species are patentably distinct to each other, the election of specie will be withdrawn hereinafter

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unless there are any dramatic changes made in future which results in election of species requirement necessary.

***Status of application***

3. Claims 23-28 are now pending and presented for the examination. All remaining claims not drawn to the elected invention are withdrawn from further consideration as being non-elected. The following rejections are made.

***Information Disclosure Statement(IDS)***

The information disclosure statement (IDS) is submitted on 12/10/2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

***Claim Objections***

4. Claims 24-28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims 24-28 are dependent on composition claims 23, but drawn to a method of claim 23.. Thus, the claims 24-28 do not further limit the subject matter recited in claim 23.

For the examination purpose, the claims 24-28 would be interpreted as composition claims, for instance all the claims 24-28 are read "A composition of claim

23...".(for those claims 24-25 and 27) , or "A composition of claim 25" (for those claims 26 and 28).

It is noted that, if applicant amends the claims 24-28 to claims that are not drawn to a composition according to claim 23, the amendment would necessitate further restriction requirement due to the reasons set forth in previous restriction requirement issued 5/19/2006.

An appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 24-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-28 recite the limitation "the method " in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 23 is drawn to a composition claim. Thus, the limitation "The method" lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by, or if alternatively, under 103(a) as being unpatentable over Pariza et al(US 5208356) alone or Pariza in view of Saebo et al(US6410761).

The claims 23-24 and 27 are drawn to a composition in tablet or capsule form, which comprises an effective amount of at least one ester containing at least one conjugated linoleic acid (e.g. 10,12-octadecadienoic acid , 9,11-octadecadienoic acid or mixtures thereof), together with a pharmaceutically acceptable carrier.

Claim 25-26 and 28 require lipid (e.g. phospholipid) instead of conjugated linoleic acid.

US'356 teaches a composition containing non-toxic esters of conjugated linoleic acid(CLA) useful as antioxidants, see abstract. US'356 also teaches four isomers produced by isomerization, for example, a mixture of four isomers(c9, c11; c9, t11; t10,c12; and c10, c12) are found, see col. 11, line 40.

It is noted that,in the basic chemistry, c9 refers to cis-9, or "9Z"; and t10 refers to trans10 or "10E" .

US'356 particularly teaches that CLA esterified in phospholipids is more effective as an antioxidant, see col.13, lines 1-2 and claim.

Most importantly, US'356 teaches a composition containing CLA esters such as CLA methyl ester, triglyceride esters of CLA and phospholipids esters, see col. 3, lines

18- 22. Furthermore, US'356 teaches a composition containing a CLA compound selected from the group consisting of the phospholipids esters of 9,11 octadecadienoic acid and the phospholipd esters of 10,12-octadecadienoic acid as patented invention. All the critical elements required by the instant claims are well taught in the cited reference except tablet or capsule dosage form. However, the claimed invention is readily envisaged by any skilled artisan to make table or capsule which is most popular dosage forms in pharmaceutical industry and market place for convenience when US356 is read in light of the following teaching at col.14, lines 1-2, where US'356 teaches that a composition can be formulated in solid or liquid product with diluents, solubilizing agents, emulsifying agents, pigments and the like for convenience.

Even if, applicant does not agree on that the teaching of US'356 is satisfy the requirement of anticipation, the tablet or capsule dosage formulation would have been readily apparent to any ordinary skill in the art when the teaching of US'356 in view of Saebo's teaching because Saebo teaches the product (oral composition) containing esters of CLA can be formulated into conventional solid or liquid formulations such as tablet and capsule using carriers such as starch, sucrose or lactorse, see col. 14, lines 21-25. Thus, one would have been motivated to make the invention into conventional oral dosage forms such as tablets or capsules because it is always desired to extend industrial applicability to improve patient satisfaction via increasing convenience.

All the claims are not patentably distinct over the prior art of the record and the claims are properly included in this rejection.

9. Claims 23-24, 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Saebo et al(US6410761 or US 6225486).

\*Since the teaching of Saebo's patents are substantially same, for the convenience, the examiner will use US'486 patent for detailed teaching.

The claims 23-24 and 27 are drawn to a composition in tablet or capsule form, which comprises an effective amount of at least one ester containing at least one conjugated linoleic acid (e.g. 10,12-octadecadienoic acid , 9,11-octadecadienoic acid or mixtures thereof), together with a pharmaceutically acceptable carrier.

Saebo et al(US' 486,hereinafter) teaches a composition containing linoleic acid (CLA) or alkyl esters and a carrier, see all abstract and claims. US'486 further teaches a pharmaceutical, nutritional or therapeutic composition containing specific species of conjugated linoleic acid such as 10,12-octadecadienoic acid , 9,11-octadecadienoic acid or mixtures thereof, see abstract.

US'486 teaches alkyesters of CLA at col. 4, lines 45-50, and also cis- or trans-isomers("Z or E isomers") of 9,11-octadecadienoic acid, see lines col. 4, 35-40 and col.6, lines 5-10. At col. 6 and examples 3-4, US486 states that 9Z, 11Z conjugated linoleic acid is encompassed by the scope of patented invention. Thus, the claim 27 is met.

US'486 teaches capsules, tablets or other oral delivery dosage forms, see col. 6, lines 21-24.

It is noted that a recitation(i.e. stimulating prostacyclin formation) of the intended use of the claimed invention recited in preamble must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 25-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saebo et al(US6410761) in view of Pariza et al(US 5208356).

Saebo's teaching is mentioned above in 102 rejection.

Claim 25-26 and 28 require lipid (e.g. phospholipid) instead of ester of conjugated linoleic acid.

US'356 teaches a composition containing a CLA ester such as CLA Alkyl esters(e.g.methyl ester), triglyceride esters of CLA and phospholipids esters, see col. 3, lines 18- 22.

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It would have been obvious to employee substitute CLA ester withphospholipids esters because US'356 teaches that CLA activity can be enhanced when CLA is incorporated into phospholipids, see col. 12, line 43-45 and col.13, lines 1-2.

US'356 teaches a composition containing a CLA compound selected from the group consisting of the phospholipids esters of 9,11 octadecadienoic acid and the phospholipd esters of 10,12-octadecadienoic acid as patented invention, see claim 1.

Thus, for greater practical applicability, one would have been motivated to make such substitution with reasonable expectation of success.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

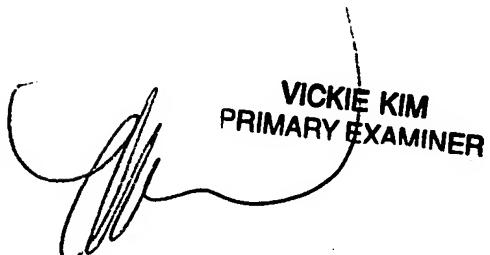
### ***Conclusion***

1. No claim is allowed.
2. All pending claims are subject to restriction/election requirement.
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



VICKIE KIM  
PRIMARY EXAMINER

Vickie Kim  
September 17, 2006  
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